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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,892	02/27/2002	Shukti Chakravarti	P-CW 4945	1524

23601 7590 07/11/2005

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EXAMINER	
PONNALURI, PADMASHRI	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,892	CHAKRAVARTI, SHUKTI	
	Examiner	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *1-13 and 16-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,15 and 19-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment and response filed on 4/18/05 has been fully considered and entered into the application.

2. New claims 19-26 have been added by the amendment filed on 4/18/05.

3. This application contains claims 1-13, 16-18 drawn to an invention nonelected with traverse in Paper filed on 8/12/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

4. Claims 1-26 are currently pending in this application. Claims 1-13, 16-18 have been withdrawn, and claims 14-15, 19-26 are currently being examined in this application.

5. The objection to the specification has been withdrawn in view of the amendment filed on 4/18/05.

6. The rejection of claim 14 as being indefinite has been withdrawn in view of the amendment filed on 4/18/05.

7. The written description rejection set forth in the previous office action has been withdrawn in view of the amendments.

8. The art rejection over Dieckgraefe et al set forth in the previous office action has been withdrawn in view of amendments.

New Claim Rejections Necessitated by the Amendment

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 14-15, 19-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is new matter rejection**.

The instant claims recite a nucleic array comprising a solid support comprising a solid support and nucleic acid probes which specifically hybridize to the mRNA of at least 5 different IBD genes shown in Table 1.

The limitation 'probes which specifically hybridize to the mRNA of at least 5 different genes shown in Table 1' claimed in Claim 14 has no clear support in the specification and the claims as originally filed. The specification in page 6, discloses 'micro-array of IBD probes for detecting transcripts of at least 5 different IBD genes'; page 31, discloses 'specifically hybridizes...' which do not support the instant claim new limitations. The subject matter claimed in the new claims (i.e. **nucleic acid probes which specifically hybridize to the mRNA of at least 5 different IBD genes shown in Table 1'**, has no support in the specification as originally filed.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

11. Claims 14-15, 19-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is written description rejection**.

The instant claims recite a nucleic array comprising a solid support comprising a solid support and nucleic acid probes which specifically hybridize to the mRNA of at least 5 different IBD genes shown in Table 1.

The specification has not disclosed the nucleic acid probes which specifically hybridize to the mRNA of at least 5 different IBD genes of Table 1. The specification description is directed to a method comprising, I) generating a first library of nucleic acid probes representative of genes expressed by intestinal tissue of an animal without apparent risks or symptoms of IBD; ii) generating a second library of nucleic acid probes representative of genes expressed by intestinal tissue of animal which has symptoms of IBD; iii) identifying the genes up or down regulated, and use thus identified genes in the method of determining a phenotype of a cell. Thus genes involved in up or down regulated in **IBD condition have to be identified and probes of these genes are generated and formed a micro arrays of the generated probes and the arrays in identifying phenotype of a cell as claimed.** The subject invention is based on findings that certain genes are differently expressed in intestinal tissue of IBD patients, compare to the normal cells.

The specification disclosure does not recite the up or down regulated IBD genes or the nucleic acid sequences of the genes identified as up or down regulated IBD genes, such that probes which hybridize to the mRNA of the genes is generated. The specification discloses that the libraries of nucleic acid probes (at least 5 genes refers to a library) for indexing the level of expression of one or more IBD genes. And the IBD probes will be isolated nucleic acids

comprising a nucleotide sequence which hybridizes under stringent conditions to a sequence of table 1(e.g., see page 3). Further the specification discloses that the nucleic acid probes for indexing the level of expression of IBD genes are nucleic acid sequences (12-40 consecutive nucleic acids) correspond to the IBD gene set. The specification discloses that 'the mRNA of a test cell is contacted with a nucleic acid probe which is at least 12 nucleotides in length...., and upto all or nearly all of a sequence which is complementary to a portion of coding sequence of a nucleic acid sequence represented in Table 1.' Thus, the IBD gene set in Table 1 is not directly used in the claimed array, only the nucleic acids that are complementary to the coding sequence of a nucleic acid of Table 1 are used. Nucleic acid sequences identical or nucleic acid sequence which is complementary to the coding sequence, and the sequence which correspond to the nucleic acid sequences of the IBD gene set in Table 1 has to be determined such that the identified nucleic acid sequences can be used as probes in the claimed array.

The claimed nucleic acid array comprises nucleic acid sequence probes identified after hybridizing with known IBD gene set (table 1), and then prepare micro arrays using the identified probes. The specification does not disclose the nucleic acid sequences, which are identified after hybridizing with the known IBD gene set. The specification has not disclosed the probe sequences by defining that the probe is any 15 of mer of known genes is not sufficient to identify which sequences would specifically hybridize to the mRNA of at least 5 different IBD genes. The specification has not disclosed which nucleic acid sequences specifically hybridize to the mRNA of IBD genes of Table 1. Without the disclosure of the probes (or nucleic acid sequences), the specification description is hypothetical.

Further IBD genes of Table 1 are only disclosed by the Gene Bank accession numbers. The specification has not disclosed the nucleic acid sequences of the IBD genes.

The specification disclosure is narrative and based on hypothetical method. The specification does not include any working examples or experiments in which the genes involved in up- or down-regulated in intestinal tissue of patients used in synthesis or preparation of the nucleic acid probes of the instant array. Thus, applicants are not in possession of the genes involved in the IBD.

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "*written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials.*" *University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1405 (1997), quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in University of California v. Eli Lilly defined the invention by function of the claimed DNA (encoding insulin)].*

Thus, it requires a representative sample of compounds and/or a showing of sufficient identifying characteristics; to demonstrate possession of the claimed generic(s). In the present instance, the claimed invention contains no identifying characteristics regarding the IBD gene sequences or the probe sequences.

The specification only discloses the well-known methods to make nucleic acid array, and does not disclose the claimed nucleic acid array probes which selectively hybridize to at least 5 different IBD genes of Table 1.

An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004).

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. > Enzo Biochem, 323 F.3d at 964, 63 USPQ2d at 1613.

The instant invention does not disclose the probes or the structure of the probes. The instant disclosure is based on a mere plan, since no working examples are present.

The claimed probe array sequences depend upon identifying the IBD genes involved in IBD, and then prepare micro arrays using the identified probes. The specification has not disclosed any working examples or experiments in which the genes involved in up- or down-regulated in intestinal tissue of a patient are identified and thus identified genes are used in synthesis or design of the probes.

The disclosure of only a method of making the invention and the function may not be sufficient to support a product claim other than a product-by-process claim. See, e.g., Fiers v. Revel, 984 F.2d at 1169, 25 USPQ2d at 1605; Amgen, 927 F.2d at 1206, 18 USPQ2d at 1021.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of

the claimed invention as a whole. See, e.g., Vas-Cath, 935 F.2d at 1565, 19 USPQ2d at 1118.

The specification in page 3 discloses that the hypothetical probes have sequences, which would be either about 80 % identical or about 100 % identical to at least about 12 to about 40 consecutive nucleotides of the genes of Table 1. The specification has not disclosed, i.e., the probes which are designed based on the above disclosure, which are roughly 80 % or 100 % identical to a 12 nucleotide fragment of the disclosed genes would hybridize to the genes in Table 1.

In the present instance, the claimed invention contains no identifying characteristics regarding the nucleic acid probes (no sequences), except they selectively hybridize to at least 5 IBD genes. The specification has not disclosed probes, which specifically hybridize to the mRNA of the genes of table 1, and the disclosure of the genes by the name and accession numbers in table 1 is clearly not representative of the scope of the nucleic acid array of the presently claimed invention.

The specification lacks written description of the claimed invention in view of no working examples, and lack of specific sequence of the probes or sequences of IBD genes.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

13. Claims 14-15, 19-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the limitation "the mRNA". There is insufficient antecedent basis for this limitation in the claim.

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Heller et al (Proc. Natl. Acad. Sci. USA. Vol. 94, pages 2150-2155, March 1997).

The instant claims recite a nucleic array comprising a solid support comprising a solid support and nucleic acid probes which specifically hybridize to the mRNA of at least 5 different IBD genes shown in Table 1.

Heller et al teach discovery and analysis of inflammatory disease related genes using cDNA micro-arrays. Heller et al teach that the cDNA micro arrays were prepared by either using all known human genes of probable significance in rheumatoid arthritis (RA), using 1056 human genes from the peripheral blood lymphocyte library (i.e., see the methods in page 2150) (reads on the instant claim array). Heller et al teach RA is a cumulative effect of several factors such as macrophages, growth factors, inflammatory cytokines, chemokines, prostaglandins, leukotrienes, matrix degrading metalloproteinases (MMPs). The reference teaches that that the differential expression of various factors in diseased RA tissue and IBD was conducted to demonstrate the utility of the micro array method to analyze complex disease by their pattern of gene expression. Heller et al disclose a 96 gene micro array design (i.e., see the results section, page 2151 and fig.1) and 1046 element array. The reference teaches that the many of the genes were common between the RA and IBD, and many genes in 1046 cDNA micro-array hybridize with probes of both RA and IBD. The reference micro-array would read on the instant claim array. And further the reference micro-array comprises probes from following genes Il-6, Il-8, GH1, Gro1, MIP, stromelysin 1. The reference teaches that the cDNA micro-array technology could provide new targets for drug development and disease therapies, and in doing so allow for improved treatment of chronic diseases. Thus, the reference clearly anticipates the claimed invention.

17. Claims 14-15, 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al (Proc. Natl. Acad. Sci. USA. Vol. 94, pages 2150-2155, March 1997) and Silverman et al (US Patent 6,331,396 B1), and Puolakkainen (G4358) and Prehn et al (G4355), Dieckgraefe et al (Gastroeteerology, vol. 114, No.4, April 1998), Dieckgraefe et al (US Patent 6,228,585 B1)

and Jones et al (The Journal of Biological Chemistry. Vol. 267, No.32, November 15, pages 23216, 1992) and specification disclosure.

The instant claims recite a nucleic array comprising a solid support comprising a solid support and nucleic acid probes which specifically hybridize to the mRNA of at least 5 different IBD genes shown in Table 1.

Heller et al, Dieckgraefe et al and Silverman et al teach micro-arrays and the role of micro-array technology in detection of complex chronic diseases.

Heller et al teach discovery and analysis of inflammatory disease related genes using cDNA micro-arrays. Heller et al teach that the cDNA micro arrays were prepared by either using all known human genes of probable significance in rheumatoid arthritis (RA), using 1056 human genes from the peripheral blood lymphocyte library (i.e., see the methods in page 2150) (reads on the instant claim array). Heller et al teach RA is a cumulative effect of several factors such as macrophages, growth factors, inflammatory cytokines, chemokines, prostaglandins, leukotrienes, matrix degrading metalloproteinases (MMPs). The reference teaches that that the differential expression of various factors in diseased RA tissue and IBD was conducted to demonstrate the utility of the micro array method to analyze complex disease by their pattern of gene expression. Heller et al disclose a 96 gene micro array design (i.e., see the results section, page 2151 and fig.1) and 1046 element array. The reference teaches that the many of the genes were common between the RA and IBD, and many genes in 1046 cDNA micro-array hybridize with probes of both RA and IBD. The reference micro-array would read on the instant claim array. And further the reference micro-array comprises probes from following genes Il-6, Il-8, GH1, Gro1, MIP, stromelysin 1. The reference teaches that the cDNA micro-array technology could provide new

targets for drug development and disease therapies, and in doing so allow for improved treatment of chronic diseases.

Dieckgraefe et al (both the references) disclose characterization of mucosal gene expression in inflammatory bowel disease (IBD) by direct hybridization to massive parallel oligonucleotide arrays. The reference discloses the use of Gene chip (refers to the solid support chip of the instant claims) expression monitoring system to examine mucosal gene expression in ulcerative colitis, Crohn's colitis to identify genotypes associated with particular disease. The reference discloses that RNA isolated from the mucosal colonial specimens was used to generate hybridization probes. The reference further discloses that light directed solid phase (refers to the support of the instant claims) combinatorial chemistry was used to generate oligonucleotide probe arrays (refers to nucleic acid probes of the instant claim array) which provide representation of nearly 7000 human cDNA and EST sequences, which would refer to the instant claim probes which selectively hybridize to at least 25 IBD genes. The reference further discloses that hybridization to the oligonucleotide arrays was sensitive, specific and reproducible.

Silverman et al teach arrays for identifying agents, which mimic or inhibit the activity of interferons. Silverman et al teach array comprising gene probes that hybridize with 50 to 10,000 interferon-stimulated and interferon repressed gene transcripts (of which some of the genes would read on the IBD genes of the instant invention).

Puolakkainen et al, Prehn et al, Pallone et al have been included in this rejection to show some of the well known genes involved in Inflammatory Bowel Disease.

Puolakkainen et al (G4358) teach distinct expression profiles of Stromelysin-s, collagenase, MMP-12 in intestinal ulcerations (refers to the IBD genes of the instant invention). Prehn et al (G4355) teach the role of TNF-α in CD, IL-18, IL-12, IL-10, IL-4 (refers to the IBD genes of the instant invention). Pallone et al teach HLA-D region antigens and their enhanced expression of inflammatory bowel disease.

Heller et al , Dieckgraefe et al and Silverman et al teach nucleic acid probe micro-arrays. Heller et al, Dieckgraefe et al and Silverman et al do not teach that the length of the probes or number of IBD genes in the array. However, it would have been obvious to one skilled in the art at the time the invention was made to use different number of known genes in the array, such that a broad range of IBD diseases or much accurate way of detection of the disease is possible. A person skilled in the art would have been motivated to use all the known genes in the array, which would allow improved detection and/or treatment of chronic diseases. And further, it was well known in the art that how to determine the length of the probes and methods of preparing the probes using the well known gene sequences. Thus, it would have been obvious in view of the specification teachings (listing of genes involved in IBD, and methods of making the probes) and the reference discussed above to make the IBD gene probe array.

18. Claims 14-15, 19-26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dieckgraefe et al (Gastroenterology, vol. 114, no. 4, G3954).

The instant claims recite a nucleic array comprising a solid support comprising a solid support and nucleic acid probes which specifically hybridize to the mRNA of at least 5 different IBD genes shown in Table 1.

Dieckgraefe et al disclose characterization of mucosal gene expression in inflammatory bowel disease (IBD) by direct hybridization to massive parallel oligonucleotide arrays. The reference discloses that parallel or high throughput methods of measuring gene expression have been recently developed which allow concurrent measurement of the expression pattern of a large number of genes. The reference discloses the use of Gene chip (refers to the solid support chip of the instant claims) expression monitoring system to examine mucosal gene expression in ulcerative colitis, Crohn's colitis to identify genotypes associated with particular disease. The reference discloses that RNA isolated from the mucosal colonial specimens was used to generate hybridization probes. The reference further discloses that light directed solid phase (refers to the support of the instant claims) combinatorial chemistry was used to generate oligonucleotide probe arrays (refers to nucleic acid probes of the instant claim array) which provide representation of nearly 7000 human cDNA and EST sequences, which would refer to the instant claim probes which selectively hybridize to at least 25 IBD genes. The reference further discloses that hybridization to the oligonucleotide arrays was sensitive, specific and reproducible.

Alternatively, the claimed invention further differs from the prior art teachings only by the recitation of 'IBD genes of table 1.' The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. Dieckgraefe et al teach oligonucleotide probe array of nearly 7000 human cDNA and EST sequences. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific probes of the instant versus the reference probes, and the solid support used in the reference array. In the absence of evidence to

the contrary, the burden is upon the applicant to prove that the claimed nucleic acid probes are not present in the reference probe array and to establish the patentable differences. See in re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ2d 1922(PTO Bd.Pat. App. & Int. 1989).

19. Claims 14-15, 19-26 are rejected under 35 U.S.C. 102(a, e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent 6,228,585 B1 (Dieckgraefe).

The instant claims recite a nucleic array comprising a solid support comprising a solid support and nucleic acid probes which specifically hybridize to the mRNA of at least 5 different IBD genes shown in Table 1.

Dieckgraefe et al disclose characterization of mucosal gene expression in Inflammatory bowel disease (IBD) by direct hybridization to massive parallel oligonucleotide arrays. The reference discloses that parallel or high throughput methods of measuring gene expression have been recently developed which allow concurrent measurement of the expression pattern of a large number of genes (i.e., see column 7). The reference discloses the use of GENECHIP (refers to the solid support chip of the instant claims) expression monitoring system to examine mucosal gene expression in ulcerative colitis, Crohn's colitis to identify genotypes associated with particular disease. The reference discloses that mRNA isolated from the mucosal colonial specimens was used to generate hybridization probes (i.e., see column 7). The reference further discloses that light directed solid phase (refers to the support of the instant claims) combinatorial chemistry was used to generate oligonucleotide probe arrays (refers to nucleic acid probes of the instant claim array) which provide representation of nearly 7000 human cDNA and EST sequences, which would refer to the instant claim probes which selectively hybridize to IBD

genes. The reference teaches that each gene is represented by 20 individual 25-mer oligonucleotide sequences (refers to the instant claim 25) (i.e., see column 7). The reference further discloses that hybridization to the oligonucleotide arrays was sensitive, specific and reproducible. The reference teaches that the fluorescence intensity for different levels of gene expression was standardized by spiking known amounts of control genes into the probe mixture (refers to the instant claim 26) (i.e., see column 7). The reference teaches human regenerating gene family (REG) role in crohn's disease and ulcerative colitis (i.e., see column 3), and discloses PAP, PSP, INGAP, and REGH as the members of the REG family (i.e., see column 3).

Alternatively, the claimed invention further differs from the prior art teachings only by the recitation of 'IBD genes of table 1.' The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. Dieckgraefe et al teach oligonucleotide probe array of nearly 7000 human cDNA and EST sequences, and further specifically teaches REG family of genes which are known to have a role in IBD. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific probes of the instant versus the reference probes, and the solid support used in the reference array. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed nucleic acid probes are not present in the reference probe array and to establish the patentable differences. See in re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ2d 1922(PTO Bd.Pat. App. & Int. 1989).

Response to Arguments

20. Applicant's arguments with respect to claims 14-15 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

21. No claims are allowed.

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PADMASHRI PONNALURI
PRIMARY EXAMINER

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

08 July 2005